REMARKS

Without adding any new matter, amendments have been made to the specification to further clarify the description of the drawings.

Response to Arguments

It is noted that the previous arguments filed in support of this application ("Liversidge") with respect to the rejections of claims 1 to 32 under Jangula (US2005/0171484) and Sempere (EP0409180) have been considered and are deemed persuasive, so that the previous objections have been withdrawn. In view of the new grounds of rejection based on Rand et al (US5137516) and Sempere, further amendments are now offered to the claims and the amended claims will be discussed in the following.

Claims Rejections - 35 USC § 103

In paragraph 5 of the second office action dated July 14, 2009, the examiner rejects claims 1 to 9, 11 to 14, 16 to 19, 21 to 24, 26 to 28, 30 and 31 under 35 USC §103(a) as being unpatentable over Rand et al in view of Sempere, cited in the first office action and discussed in detail in the response to that first office action. As a consequence of this obviousness rejection, the claims (and particularly the principal apparatus claim 1) have been revised in order to distinguish the claimed structure of Liversidge from the device described in Rand et al.

Specifically, claim 1 of Liversidge has been revised so as to describe the structure of the plug 35 and its inter-relationship with the carrier 20 and the protective sheath 17 in more detail, thereby emphasising the differences between that plug 35 and the end cap 132a of Rand et al. Further, there has been minor revision to the functional clause at the end of claim 1 of Liversidge, in order better to explain how the claimed structure of Liversidge operates and is used in practice, since this clearly brings out the differences between Liversidge and Rand et al.

In Rand et al, there is a cartridge comprising a first cap 131 and a second cap 132, the two caps together being fitted on to a syringe assembly 23 having a needle 19. When that assembly is to be fitted to a syringe actuating device 10, cap 131 is removed and "the second cap 132 becomes the main cap of the entire administering device" - see column 11, lines 15 to 17 of Rand et al.

The end cap 132a merely serves to close the end of the second cap 132. In the second office action, page 3, sub-paragraph b, the examiner stated that the end cap 132a is "slidably mounted on the carrier and [is] projectable from the forward end thereof". The examiner is here mistaken, as is apparent from column 11, line 24 of Rand et al. Here it is stated that "...the second cap 132 includes an end cap 132a which is fixedly mounted therein". It is apparent that the end cap 132a serves merely to close the second cap 132 and is ***not slidably mounted*** in any way relative to that second cap. The end cap 132a has no other function than to close the second cap 132 and is not at all the equivalent of sliding plug 35 of Liversidge.

Further, there is another very important structural difference between Rand et al and Liversidge. In Rand et al, the equivalent structure to the "protective sheath 17" of Liversidge is rubber septum 20, which serves to seal the forward sharp end of the needle. However, that septum is a part of the second cap 132 and its fixed end plug 132a; it is not a part of the syringe and its needle, unlike the situation with Liversidge. At no time is the septum 20 separated from the second cap 132. It is part of the needle assembly only so long as cap 132 is fitted to the syringe.

Even though the rubber septum 20 of Rand et al is fitted permanently in the second cap 132 and its end cap 132a, and so can be distinguished from the protective sheath 17 of Liversidge, there is another very important difference between the rubber septum 20 and the protective sheath of Liversidge. In order that the claimed structure of Liversidge may have the specified functionality, it is

an essential feature that the protective sheath is "substantially rigid" - see page 7, line 29 and page 9, line 8 of the published international specification. The sheath must have this characteristic in order that it is capable of withstanding a compressive load so that it may push the plug 35 forwardly, in the course of fitting the device to an injector including the sheathed needle. The rubber septum 20 of Rand et al must be of a soft pliable rubber else the needle tip would be damaged in the course of manufacture of the syringe assembly 23. If the protective sheath 17 of Liversidge were of a similar material to that of the rubber septum of Rand et al, it would be incapable of pushing the plug 35 forwardly, in the course of fitting the device of Liversidge to the injector already having the needle (with its protective sheath) fitted thereto.

Claim 1 of Liversidge has therefore been amended firstly to specify that the protective sheath 17 is "substantially rigid" and secondly to define the plug 35 as having a wall engageable by the protective sheath such that the plug can be pushed forwardly thereby, in the course of fitting the device to the injector.

Taking into account the changes now offered to claim 1, it is submitted that the claim is adequately distinguished from Rand et al, taken by itself or in combination with Sempere as will be discussed below. Rand et al neither teaches nor suggests any kind of slidable plug having a normal position and an indicating position, to show that the needle of an injector has been de-sheathed and so is ready for use. In addition, Rand et al does not disclose the use of a device which is capable of de-sheathing a separate needle assembly having a protective sheath by fitting the device to that needle assembly and then withdrawing the device from the needle, so leaving the needle ready to perform an injection. Rather, in the case of Rand et al the equivalent of the protective sheath (that is, the rubber septum 20) is an integral part of the second cap 132 which protects the needle from manufacture of the device as a whole, but which simply is pulled away from the needle with the second cap 132 when the injector is to be used.

As noted by the examiner on page 3 of the second office action, Rand et al does not teach a cylindrical sleeve assembly within the outer cylindrical wall. The examiner then relies on the reference to Sempere, to show that "it would have been obvious to a person having ordinary skill in the art... to modify the handling device of Rand et al, with a sleeve, bushing and spring means, as taught by Sempere... to provide protection of the needle by enclosing the needle automatically in the sleeve and bushing...". Though this suggestion of the examiner is traversed, it is not directly relevant to the claimed structure of Liversidge, since the combination of Rand et al with Sempere as suggested by the examiner would not lead to the claimed structure of Liversidge, of having a substantially rigid protective sheath, a plug slidably mounted within the carrier for movement between inactive and indicating positions, and the plug being moved by interengagement of the protective sheath with a wall within the plug, in the course of the fitting of the device to an injector.

Rand et al is wholly silent on these essential features of Liversidge and so too is Sempere; as a consequence the combination of Rand et al with Sempere cannot lead to the invention of Liversidge as now defined by revised claim 1.

In view of the above, it is submitted that claim 1 and all of the claims dependent on claim 1 are allowable.

On page 4 of the office action, the examiner has rejected claim 17 of Liversidge on the basis of Rand et al and Sempere but has suggested that though Rand et al is silent on the colour of end cap 132a, it would have been an obvious matter of design choice to modify the colour of the plug. The examiner then indicates that Liversidge "has not disclosed that contrasting colours provide an advantage, are used for a particular purpose or solve a stated problem".

The attention of the examiner is drawn to page 5 of the international specification as published, and in particular the paragraph starting at line 22. There it is stated that "...the plug may have a highly visible colour to ensure it

gives an adequate warning of the fact a needle has been unsheathed". Further, at the foot of page 9, it is stated that the plug projecting from the carrier indicates to a user that the needle is unsheathed; by providing the plug with a colour different from that of the carrier, this becomes yet more apparent to a user.

Claims 21 to 24, 28 and 30 have been rejected on the basis of Rand et al but on page 5 of the office action, the examiner refers to the carrier of Rand et al having an outer cylindrical wall and coaxial therewith an inner tube which is a close sliding fit over the protective sheath of a needle, referring to Figures 23 and 24 of Rand et al (sub-paragraph a. on page 5). For the reasons which have been explained above, the substantially rigid sheath of Liversidge can clearly be distinguished from the rubber septum 20 of Rand et al. With Rand et al, the septum 20 is permanently secured within the second cap 132 and is not the equivalent structure of the rigid sheath of Liversidge. In any event, and as will be appreciated from Figures 4, 6, 14 to 16 and 19 to 24 of Rand et al, the rubber septum 20 is not just a removable protection for the needle. Rather, the rubber septum envelopes the needle, the needle mount and a boss at the forward end of the injection device. Though offering protection to the needle, the function of the rubber septum is not the same as that of the rigid sheath of Liversidge. Having regard to the configuration at the forward end of the syringe, it is clear that the rubber septum must be resiliently flexible else it would not be possible to withdraw the syringe from that septum.

Referring again to page 5 of the office action, the examiner indicates that Rand et al does not teach certain aspects claimed in claims 21 to 24, 28 and 30 but the examiner then goes on to say that these features would have been obvious to a person having ordinary skill in the art to modify Rand et al as taught by Sempere so resulting in the invention of these claims. As has been explained hereinbefore, a combination of Rand et al and Sempere cannot lead to the invention of Liversidge

since both Rand et al and Sempere are wholly silent on the defined essential features of Liversidge.

As regards claim 31, this is again rejected on the basis of Rand et al and Sempere. The same arguments apply here, as indeed has been noted by the examiner in line 2 of page 6 of the office action and insofar as it is submitted that the combination of Rand et al and Sempere cannot lead to the invention of claim 1, equally that combination cannot lead to the invention of claim 31.

Claims 10 and 25 have been rejected under 35 USC §103(a) on the basis of Rand et al and Sempere and further in view of Jangula (US 2005/0171484). Yet again, the combination of Rand et al and Sempere cannot lead to the invention of claim 1, on which claim 10 is dependent, nor to the invention of claim 21, on which claim 25 is dependent. The addition of Jangula cannot meet the fundamental fact that the combination of Rand et al and Sempere does not lead to the inventions of claims 1 and 21. In any event, the examiner has already recognised in paragraph 3. on page 2 of the current office action that Jangula when taken in combination with Sempere does not lead to Liversidge even without the further amendments now offered to claims 1 and 21.

Claims 15, 20, 29 and 32 have further been rejected under 35 USC §103(a) as unpatentable over Rand et al and Sempere, and further in view of Pizzino (US 4,702,737). The situation as regards Rand et al and Sempere has fully been discussed above and will not here be repeated other than briefly to say that neither Rand et al nor Sempere teach or suggest the essential features of Liversidge as now defined in claims 1 and 21. Pizzino simply describes an injector device including a screw-thread on a boss at the forward end of the syringe, and a needle having an internally threaded hub which is threaded on to the externally threaded boss of the syringe. Such an arrangement is very widely known and understood in this art with the most common configuration for a conventional syringe being known as a Luer Lock Connector. Injection pens use screw-threaded

connectors with much finer threads but again are very widely employed and well known.

Since Pizzino merely teaches the use of a screw-threaded connection, the addition of Pizzino to a combination of Rand et al and Sempere cannot assist a rejection of claims 15, 20, 29 and 32.

Conclusion

Based on the above, it is submitted that independent claims 1, 21, 31 and 32, along with the remaining claims in this application which are all dependent from these independent claims, are distinguished from the cited prior art and are therefore in a condition for allowance, after taking into account the amendments offered to these claims.

A sincere effort has been made to place this application in a suitable condition for allowance and such action is earnestly requested.

Respectfully submitted,

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